

TITLE 183 - NEBRASKA DEPARTMENT OF HEALTH/FINANCIAL ASSISTANCE/REGULATIONS

CHAPTER 2 - RULES AND REGULATIONS GOVERNING, GRANTS AND CONTRACTS FOR RESEARCH OF CANCER OR SMOKING DISEASE OR BOTH

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TITLE 183 - NEBRASKA DEPARTMENT OF HEALTH

CHAPTER 2 - RULES AND REGULATIONS GOVERNING GRANTS AND CONTRACTS FOR RESEARCH OF CANCER OR SMOKING DISEASE OR BOTH

GRANTS FOR RESEARCH

001 DEFINITIONS - GRANTS FOR RESEARCH

001.01 Definitions. As used in these Regulations the following terms shall have the following meanings:

001.01A Cancer shall mean all malignant neoplasms regardless of the tissue of origin, including malignant lymphoma and leukemia.

001.01B Smoking disease shall mean diseases whose causes are linked to smoking including, but not limited to, cardiovascular, pulmonary, and gastrointestinal diseases.

001.01C Director shall mean the Director of Health.

001.01D Department shall mean the Department of Health.

001.01E Act shall mean sections 81-637 to 81-640, Reissue Revised Statutes of Nebraska, 1943.

001.01F Grant shall mean a money payment awarded by the Department of Health to a researcher of cancer or smoking disease, or both, for the purpose of carrying out a project.

001.01G Grantee shall mean the University of Nebraska.

001.01H Principal investigator shall mean a single individual, designated by the grantee in the grant application and approved by the Director, who is responsible for the scientific and technical direction of the project or program.

001.01I Project or program shall mean the particular activity as described in the application approved by the Director or as modified through amendments approved by the Director within the area of research of cancer or smoking disease which is supported by a grant award issued under these regulations.

002 ELIGIBLE PROJECTS FOR GRANT FOR RESEARCH

002.01 Permissible Activities Within Projects. A project found by the Director to be a research project meeting the criteria for a grant established by these Rules and Regulations in the area of research of cancer or smoking disease, or both, shall be eligible for a grant award. Eligible projects shall consist of laboratory, clinical, population, behavioral, epidemiological, field, statistical, basic, applied or other types of investigations, studies or experiments or combinations thereof and may either be limited to one, or a particular aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive investigation and involving multiple discipline, facilities and resources, providing the project as a whole meets the other standards established by these Regulations.

003 APPLICATION PROCESS FOR GRANT

003.01 Submittal Deadline Notification. The University of Nebraska shall be notified by the Director of a sixty-day period for the acceptance of proposals.

003.02 Notification shall be made by the Director to individuals who have submitted proposals during the two previous years, to the Systems Office of the University,

appropriate colleges or departments of the University of Nebraska, and other individuals who indicate their interest.

003.03 Submitting Proposals. To be considered for funding, a grant proposal must be presented to the Director during a period which the Director has designated for accepting grant proposals on 8 1/2 x 11 inch white paper.

003.04 Content of Application. A grant proposal must include the following information at a minimum:

003.04A Must identify the prospective principal researcher and indicate said individual's affiliation with the University of Nebraska.

003.04B Must provide a summary of the proposal worded in non-technical language, except where technical terms cannot be avoided to convey intent;

003.04C Must provide an itemized list of all proposed expenditures to be made with the grant;

003.04D Must demonstrate the relevancy of the proposal to the furthering of cancer and smoking diseases research;

003.04E Must demonstrate the feasibility of the applicant's proposal;

003.04F Must demonstrate that the facilities, personnel, and expertise necessary to conduct the proposed work are available to the applicant.

003.04G Must provide evidence of the quality of the applicant's prior or existing programs for research of cancer and smoking diseases or the applicant's potential for developing new programs for such research; and

003.04H Must provide a statement of hypothesis to be tested and an indepth discussion of the methodology to be employed in testing it.

003.05 Conduct of Review. The review of proposals shall be completed by the Director and notification concerning awards shall be made within one hundred eighty days of the application deadline.

004 EVALUATION AND DISPOSITION OF APPLICATIONS FOR GRANT

004.01 Evaluation. The Director when making grants to the grantee pursuant to this Act shall consider the following criteria for programs or projects in order to receive funding:

004.01A The relevancy of the applicant's proposal to the furthering of research of cancer and smoking diseases;

004.01B The feasibility of the applicant's proposal;

004.01C The availability of other sources of funding for the applicant's proposal;

004.01D The facilities, personnel, and expertise available to the applicant for use in the proposal;

004.01E Evidence of the quality of the applicant's prior or existing programs for research of cancer and smoking diseases or the applicant's potential for developing new programs for such research; and

004.01F That the applicant is the University of Nebraska.

005 RESEARCH PROJECT GRANT AWARDS

005.01 General. Any funds granted shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, these regulations, and the terms and conditions of the grant award. The awarding of a grant is dependent upon the appropriation of adequate funds by the Legislature.

005.02 Notice of Grant Award. The notice of a grant award specifies the length of the project period. The grant will initially be for no more than one year and continuation grant awards will also be for no more than one year at a time. Funding of continuation grants shall be subject to the availability of funds and submission of a continuation grant application, provided that, the proposal meets the applicable criteria.

006 USE OF GRANT FUNDS

006.01 General. Grant funds may be utilized for payment of the salaries of personnel participating in the project, but not for the payment of overhead. A progress report, including time and effort as well as other indicator shall be submitted a grantee after the grant has been in effect for a period of six months. If a progress report is not submitted, is submitted late, is incomplete, or indicates a lack of measurable progress, the transmittal of further grant funds may be suspended by the Director until corrective measures have been taken eliminating the deficiencies. Grant funds shall be subject to audit by the Department after the grant has been in effect for a period of six months and for each six months thereafter.

006.02 Delegation of Fiscal Responsibility. The grantee may not in whole or in part delegate or transfer to another responsibility for the use or expenditure of grant funds but this does not prohibit or restrict a grantee from subcontracting for specific services. A grantee shall not subcontract for all necessary services with a single entity to implement the project. The grantee may not make any subgrant to or enter into any subcontract with any school or institution of learning not owned or exclusively controlled by the State of Nebraska or a political subdivision thereof.

006.03 Changes in Project or Program. The permissible changes by the principal investigator in the approved project or program shall be limited to changes in methodology, approach or other aspects of the project or program to expedite achievement of the project's research objectives, including changes that grow out of the approved project and serve the best scientific strategy, provided that, as thus changed, the project still furthers the research of cancer and smoking diseases. Any other changes constitute a breach of the grant conditions. Any change in objectives of the approved application shall constitute a breach of the grant conditions unless first approved by the Director.

CONTRACTS FOR RESEARCH

007 DEFINITIONS - CONTRACTS FOR RESEARCH

007.01 Definitions. As used in these Regulations the following terms shall have the following meanings:

007.01A Cancer shall mean all malignant neoplasms regardless of the tissue of origin, including malignant lymphoma and leukemia.

007.01B Smoking disease shall mean diseases whose causes are linked to smoking including, but not be limited to, cardiovascular, pulmonary, and gastrointestinal diseases.

007.01C Director shall mean the Director of Health.

007.01D Act shall mean Nebraska Revised Statutes sections 81-637 to 81-640.

007.01E Contract shall mean an agreement between the Department and the contractor in which in return for consideration of funding, the contractor shall carry out in a specified manner a specified project or program to further the research of cancer and smoking diseases.

007.01F Request for Proposals shall mean a Departmental solicitation to prospective offerors or contractors, under procedures for negotiated contract, to submit a contract proposal for research of cancer or smoking disease, or both.

007.01G Contractor shall mean the University of Nebraska or any other postsecondary institution having a college of medicine located in the State of Nebraska.

007.01H Contract application or proposal shall mean a written offer to enter into a contract for research of cancer or smoking disease, or both submitted to the Director by a contractor and including as a minimum a description of the nature, purpose, duration, benefits and cost of the contract project and the methods personnel and facilities to be utilized in carrying it out, and meeting the other standards specified by these Regulations.

007.01J Principal investigator shall mean a single individual designated by the contractor in the contract proposal and approved by the Director, who is responsible for the scientific and technical direction of the contract project or program.

007.01J Contract project or program shall mean the particular activity, as described in the application approved by the Director or as modified through amendments approved by the Director, within the area of research of cancer or smoking disease which is supported by a contract award issued under these Regulations.

008 ELIGIBLE PROJECTS FOR CONTRACT FOR RESEARCH

008.01 Permissible Activities Within Projects Eligible projects shall consist of laboratory, clinical, population, behavioral, epidemiological, field, statistical, basic, applied or other types of investigations, studies or experiments or combinations thereof, and may either be limited to one, or a particular aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive investigation and involving multiple disciplines, facilities and resources, providing the project as a whole meets the other standards established by these Regulations.

009 APPLICATION PROCESS FOR CONTRACT.

009.01 Submittal Deadline Notification. The University of Nebraska or any other postsecondary institution having a college of medicine located in the State of Nebraska shall be notified by the Director of a sixty-day period for the acceptance of proposals.

009.02 Notification shall be made by the Director to individuals who have submitted proposals during the two previous years, to the Systems Office of the University of Nebraska, appropriate colleges or departments of the University of Nebraska, all other postsecondary institutions having a college of medicine located in the State of Nebraska and appropriate colleges or departments of the same, and other individuals who indicate their interest.

009.03 Submitting Proposals. To be considered for funding, a contract proposal must be presented to the Director during a period which the Director has designated for accepting contract proposals on 8 1/2 x 11 inch white paper.

009.04 Content of Application. A contract proposal must include the following information at a minimum:

009.04A Must identify the prospective principal researcher and indicate said individual's affiliation with the University of Nebraska or other postsecondary institution having a college of medicine located in the State of Nebraska;

009.04B Must provide a summary of the proposal worded in non-technical language, except where technical terms cannot be avoided to convey intent;

009.04C Must provide an itemized list of all proposed expenditures to be made with the grant;

009.04D Must demonstrate the relevancy of the proposal to the furthering of cancer and smoking diseases research;

009.04E Must demonstrate the feasibility of the applicant's proposal;

009.04F Must demonstrate that the facilities, personnel, and expertise necessary to conduct the proposed work are available to the applicant;

009.04G Must provide evidence of the quality of the applicant's prior or existing programs for research of cancer and smoking diseases or the applicant's potential for developing new programs for such research; and

009.04H Must provide a statement of hypothesis to be tested and an indepth discussion of the methodology to be employed in testing it.

009.05 Conduct of Review. The review of proposals shall be completed by the Director and notification concerning awards shall be made within one hundred eighty days of the application deadline.

010 EVALUATION AND DISPOSITION OF CONTRACT PROPOSALS OR APPLICATIONS

010.01 Evaluation. The Director when awarding contracts to the contractor pursuant to this Act shall consider the following criteria for contract projects or programs in order to receive funding:

010.01A The relevancy of the contract proposal to the furthering of research of cancer and smoking diseases;

010.01B The feasibility of the contract proposal;

010.01C The availability of other sources of funding for the contract proposal;

010.01D The facilities, personnel, and expertise available to applicant for use in the contract proposal;

010.01E Evidence of the quality of the applicant's prior or existing programs for research of cancer and smoking diseases or the applicant's potential for developing new programs for such research; and

010.01F That the applicant is the University of Nebraska or any other postsecondary institution having a college of medicine located in the State of Nebraska.

011 CONTRACT AWARDS

011.01 General. Any contract funds awarded shall be expended solely for the purposes which the funds were awarded in accordance with the approved contract proposal or application and budget, these Regulations, and the terms and conditions of the contract award. The awarding of a contract is dependent upon the appropriation of adequate funds by the Legislature.

011.02 Notice of Contract Award. The notice of contract award specifies the length of the contract project period. The contract award will initially be for no more than one year and continuation contract awards will also be for no more than one year at a time. Funding of continuation contract awards shall be subject to the availability of funds and submission of a continuation contract proposal, provided that, the proposal meets the applicable criteria.

012 USE OF CONTRACT FUNDS

012.01 General. Contract funds may be utilized for the payment of the salaries of personnel participating in the contract project, but not for the payment of overhead. A progress report, including time and effort as well as other indicators, shall be submitted by a contractor after the contract has been in effect for a period of six months. If a progress report is not submitted, is submitted late, is incomplete, or indicates a lack of measurable progress, the transmittal of further contract funds may be suspended by the Director until corrective measures have been taken eliminating the deficiencies. Contract funds shall be subject to audit by the Department after the contract has been in effect for a period of six months and for each six months thereafter.

012.02 Delegation of Fiscal Responsibility. The contractor may not in whole or in part delegate or transfer to another responsibility for the use or expenditure of contract funds, but this does not prohibit or restrict a contractor from subcontracting for specific services. A contractor shall not subcontract for all necessary services with a single entity to implement the contract project.

012.03 Changes in Contract Project or Program. The permissible changes by the principal investigator in the approved contract project or program shall be limited to changes in methodology approach or other aspects of the contract project or program to expedite achievement of the contract project's research objectives, including changes that grow out of the approved contract project and serve the best scientific strategy, provided that, as thus changed, the project still furthers the research of cancer and smoking diseases. Any other changes constitute a breach of the contract. Any change in objectives of the

approved application shall constitute a breach of the contract unless first approved by the Director.

SOURCE: Nebraska Revised Statutes Sections 81-637 to 81-640

008.10A Allowable Costs:

008.10A1 Salaries and fringe benefits of staff investigators, senior project leaders, or other staff directly involved in the research.

008.10A2 Salary for the principal investigator not to exceed 25% of the institutional annual base salary.

008.10A3 Equipment directly linked to the research.

008.10A4 Supplies, such as laboratory supplies and office supplies.

008.10A5 Services, such as dishwashing services, directly related to the research.

008.10A6 Consultants or subcontracts, except that the institution shall not subcontract for all necessary services with a single entity to implement the project.

008.10A7 Patient costs. If justified, charges for blood samples, X-rays, physical examinations, or comparable procedures are allowed for human subjects involved in the research.

008.10A8 Publication costs up to \$15,000 as described below:

008.10A8(a) The paper reports work supported by the grant or contract;

008.10A8(b) The charges are levied impartially on all papers published by the journal whether or not by government sponsored authors.

008.10A8(c) Other publication costs are allowable if the publication reports work supported by the grant or contract and if the costs of publication for the type of publication are routinely borne by the research institution.

008.10A9 Other operating expenses, such as postage, data processing, long distance phone calls required by the nature of the research, photocopying, correspondence, reports, obtaining samples.

008.10A10 Renovations and alterations directly related to the research.

008.10B Unallowable Costs:

008.10B1 Travel expenses.

008.10B2 Indirect costs or overhead expenses, such as rent, general administrative costs.

008.10B3 Building construction.

008.10B4 Direct patient treatment costs or costs of clinical trials.

008.10B5 Any other expenses not directly related to the research.

008.11 The (Contractor) (Grantee) and any of its subcontractors shall not discriminate against any employee or applicant for employment to be employed in the performance of the (contract) (grant) with respect to hire tenure, terms, conditions, or privileges of employment because of the race, color, religion, sex, age, disability or national origin of the employee or applicant.

The (Contractor) (Grantee) assures that it will comply as applicable with the Americans with Disabilities Act of 1990 and its implementing regulations.

008.12 The (Contractor) (Grantee) shall comply with Neb. Rev. Stat. Sections 81-638 to 81-640.01 and these regulations.

008.13 The (Contractor) (Grantee) shall have and maintain a Drug-Free Workplace Policy governing the conduct of its employees.

008.14 All publications supported by funds awarded under Neb. Rev. Stat. Sections 81-638(2)(3) and 81-639 to 640.01 and these regulations must bear an acknowledgment and disclaimer as appropriate, such as:

This publication (journal article, etc.) was supported by revenue from Nebraska cigarette taxes awarded to (name of Grantee or Contractor) by the Nebraska Department of Health. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the State of Nebraska or the Nebraska Department of Health.